

## **Session 2 Summary**

The EFSPI statistical methodology leaders, represented by Mouna Akacha (Novartis) and Kaspar Rufibach (Merck KGaA), presented the four priority topics of the group which are

1. Application of Bayesian methods in drug development
2. Covariate adjustment
3. A framework to appraise statistical methods building on ICH M15
4. Specific topics related to estimands

and why the EFSPI statistical methodology leaders had made these topics their priority.

In the breakout group discussions the EFSPI statistical leaders identified tangible actions how the EFSPI Stat Leaders and EFSPI Stats Methodology Leaders groups can support each other to commercialize the four priority topics within their companies and beyond.

Concrete proposals were

- Developing lists of arguments for the priority topics
- Working up of "cold cases" and Health Authority feedback to help kickstart discussions in companies
- Generating white papers targeting drug developers (not "only" statisticians), and
- Starting blog(s) and newsletter(s).

The EFSPI statistical methodology leaders will move forward by building all this input in concrete action plans including timelines.